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10/528,302	03/17/2005	Christian Hubert Weidl	29827/41023	6447

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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,302	WEIDL ET AL.	
	Examiner	Art Unit	
	Michael N. Orlando	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-24* is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 21-24* is/are rejected.

7)☒ Claim(s) *11-13, 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

`Arrangement of the Specification`

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The disclosure is objected to because of the following informalities: The specification is objected to for failing to include the proper headings as stated above.

Appropriate correction is required.

3. The spacing of the lines of the specification is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application exceeds the length of 20 pages and is therefore considered to be lengthy.

Claim Objections

5. Claims objected to because of the following informalities: In claim 24 the phrase "applying a hydrogel" should be changed to -applying the hydrogel-. Appropriate correction is required.

6. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 is drawn to a material property of the adhesive claimed in claim 1 and it is inherent that the adhesive taught in claim 1 would also contain said stability index therefore this claim fails to further limit the invention.

Double Patenting

7. Claims 12 and 23 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 11 and 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-13 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. (WO 00/45698).

Regarding claims 1, Heard et al. teaches an electrically conductive skin-interface substrate material in the form of a film that possesses adhesive properties so as to allow it to adhere to the skin of patients (page 5, lines 14-17). Said adhesive film is taught to contain a polyhydric alcohol (non-ionic humectant) in the amount of 25-75% (referred by 25-75pph) to plasticize the organic polymer and act as a humectant to absorb moisture and promote conductivity (page 12, lines 6-12). Furthermore it is taught that the conductive organic polymer contains acrylic acid in the amount of 25-75% (page 11, lines 1-3). Also, it is taught that the conductive polymer has a capacity for retaining water, which further promotes conductivity (page 14, lines 1-4) and it is taught that the polymer may contain as much as 25% (25pph) of distilled water (page 13, line 28). It is taught that the acrylic acid polymer is a copolymer with N-vinylpyrrolidone being added in the range of 2-30% (2-30pph) (page 11, lines 1-7) and this copolymer may also contain acrylamide as a cross-linking agent to facilitate cohesivity through cross-linking (page 11, line 7-17). It is clear that the acrylic acid/N-vinylpyrrolidone copolymer is cross-linked through the presence of acrylamide to become a cross-linked hydrophilic polymer and further given the concentrations taught (page 11, lines 1-7; page 13, lines 20-28) it is also apparent that that the acrylic acid component accounts

for the majority (i.e. over 80 mole% when N-vinylpyrrolidone is 2% and acrylic acid is 55%). It is recognized by the examiner that given the ranges of acrylic acid and N-vinylpyrrolidone taught above (25-75% and 2-30% respectively), the crosslinking would primarily yield a cross-linked copolymer within the range of 10-60% especially given the suggested amounts of N-vinylpyrrolidone and acrylic acid. It is well known in the art that acrylic acid has a pKa above 3 and moreover that pKa is specifically known to be 4.25. Heard et al. also teaches that the acrylic acid component is partially neutralized with basic potassium or sodium oxide for example in the amount of 33 to 67 mole% of the acrylic acid being neutralized (page 13, lines 30-34). It is well known in the art that the neutralization of acrylic acid with basic potassium or sodium oxide would generate acrylic acid in the salt form and moreover since as much as 67 mole% is being neutralized this would inherently yield over 60% mole% in the salt form. Heard et al. fails in certain instances to specifically point out the ranges for the aforementioned components falling within the claim limitations. Also, it is not specifically taught that the peel strength of the conductive polymer on PET is between 0.3 and 3.0 N/cm with a stability index measured after 14 days of SI_x14 below 0.10.

Although many of the ranges taught by Heard encompass or satisfy those in the claim limitations, due to fact that the claim limitations switch between mole% and wt% it is difficult to discern their exact correlation; however, it should be recognized that the generalized concept has been substantially satisfied by the teaching of Heard et al. and moreover it is within the scope of the invention to have identified the ranges taught by Heard et al. and specifically incorporate those in the claim limitations since in all cases

they are at least encompassed by those taught. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the specific ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ). Although it is not specifically taught that the peel strength of the conductive polymer on PET is between 0.3 and 3.0 N/cm with a stability index measured after 14 days of SI_x14 below 0.10 it is inherent that if the components of the adhesive are the same as those within the claim limitations, said adhesive would also contain the same or substantially similar peel strength and stability index. Furthermore given that it was recognizably well known in the art that stability is an important factor in adhesives it would have been obvious at the time of the invention to minimize the stability index of the adhesive taught by Heard et al. while staying within the scope of the invention disclosed.

Regarding claim 2, the claimed limitation taught to be inherent within the invention disclosed by Heard et al. in claim 1 as seen above in claim 1 arguments.

Regarding claim 3, Heard et al. is silent as to the presence of an alkanolamine. Although not explicitly taught to be free of alkanolamines there is no alkanolamines within either the formulation of the adhesive or the byproducts taught by Heard et al. and the reasonable conclusion is that the conductive organic polymer adhesive taught by Heard et al. is therefore free of said alkanolamines.

Regarding claim 4, Heard et al. teaches that the conductive organic polymer adhesive of claim 1 contains acrylic acid in the amount of 25-75pph (page 11, lines 1-3). It is well known in the art that acrylic acid is a weak acid.

Regarding claim 5, Heard et al. teaches that the acrylic acid component defined in claim 1 is partially neutralized with basic potassium or sodium oxide. Specifically it is taught that 33 to 67 mole% of the acrylic acid is neutralized (page 13, lines 30-34). It is well known in the art that the neutralization of acrylic acid with basic potassium or sodium oxide would generate acrylic acid in the salt form and moreover since as much as 67 mole% is being neutralized this would inherently yield over 60% mole% in the salt form while not exceeding the amount of 67 mole% in the salt form. Heard et al. does not explicitly teach the claimed range, but the range taught by Heard et al. clearly falls within the claimed range.

Heard et al. disclosed the claimed invention except for the exact range, but it is noted that the range taught is substantially similar. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the specific ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ).

Regarding claim 6, Heard et al. teaches a conductive polymer adhesive of claim 1 that contains a polyhydric alcohol to plasticize the organic polymer and act as a humectant to absorb moisture while promoting conductivity (page 12, lines 6-12).

Regarding claim 7, Heard et al. teaches that the acrylic acid polymer is a copolymer with N-vinylpyrrolidone (page 11, lines 1-7) and this copolymer may also contain acrylamide as a cross-linking agent to facilitate cohesivity through cross-linking (page 11, line 7-17). It is clear that the acrylic acid/N-vinylpyrrolidone copolymer is cross-linked through the presence of acrylamide and further given the concentrations taught (page 11, lines 1-7; page 13, lines 20-28) it is clear that the acrylic acid component accounts for the majority (i.e. over 80 mole%) of the said copolymer. The specific values are not specifically taught such as to satisfy only those instances wherein the acrylic acid component accounts for over 90 mole%, but given the upper bound of the acrylic acid taught (75pph) and the lower bound of N-vinylpyrrolidone taught (2pph) it is clear that a substantial majority (i.e. >90 mole%) is consistent of the acrylic acid component.

Although the range taught by Heard et al. encompasses a larger range than just those greater than 90 mole% it should be recognized that the generalized concept has been substantially satisfied by the teaching of Heard et al. and moreover it is within the scope of the invention to recognize the ranges taught and specifically incorporate those in the claim limitations since in this specific case they are already substantially encompassed by those taught. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the specific ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ).

Regarding claim 8, Heard et al. teaches that the conductive organic polymer adhesive (hydrogel) of claim 1 having a pH value of 4.3-4.7 (page 18-20, table 1).

Regarding claim 9, Heard et al. teaches that the conductive organic polymer adhesive of claim 1 contains acrylic acid in the amount of 25-75pph (page 11, lines 1-3). It is well known in the art that acrylic acid is a weak acid. Heard et al. also teaches the conductive organic polymer contains a polyhydric alcohol to plasticize the organic polymer and act as a humectant to absorb moisture while promoting conductivity (page 12, lines 6-12). Said polyhydric alcohol is taught to preferably be glycerol (page 12, lines 11-12).

Regarding claim 10, Heard et al. teaches that the acrylic acid component of claim 1 is partially neutralized with basic potassium or sodium oxide (page 13, lines 30-34; page 27, lines 4-9). It is well known in the art that the neutralization of acrylic acid with basic potassium or sodium oxide would generate acrylic acid in the salt form and given the nature of the metal elements taught (potassium and sodium) the counterion would inherently be a monovalent metal ion (i.e. K+ or NA+).

Regarding claims 11 and 12, these claims are identical in nature and as per the reasons discussed in claim 1 arguments they are an obvious variant, which is found to be inherent within the invention taught by Heard et al (see claim 1 argument).

Regarding claims 13 and 23 these claims are identical in nature and as per the reasons discussed in claim 1 arguments they are an obvious variant, which is found to be inherent within the invention taught by Heard et al (see claim 1 argument).

Regarding claim 21, Heard et al. teaches the conductive organic polymer adhesive of claim 1 contains acrylic acid in the amount of 25-75pph (page 11, lines 1-3). It is well known in the art that acrylic acid is a weak acid.

Regarding claim 22, Heard et al. teaches the conductive organic polymer of claim 1 contains a polyhydric alcohol to plasticize the organic polymer and act as a humectant to absorb moisture while promoting conductivity (page 12, lines 6-12). Said polyhydric alcohol is taught to preferably be glycerol (page 12, lines 11-12).

Regarding claim 24, Heard et al. teaches the adhesive layer of claim 1 as discussed above. Heard et al. further teaches a conductive member (i.e. a medical electrode), which has upon the underside an electrically conductive skin-interface substrate with adhesive properties (adhesive taught in claim 1) that can be used to facilitate the binding of said conductive member to the skin of a patient (page 5, lines 3-22).

12. Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. (WO 00/45698) in view of Kim (WO 02/053605).

Regarding claims 15-19, the adhesive of claim 1 is taught as seen above. Heard et al. is silent as to the presence of any residual monomers. Although it not explicitly taught that there is below 10000ppm of residual monomers there is no residual monomers within the byproducts taught by Heard et al. and the reasonable conclusion is that the conductive organic polymer adhesive taught by Heard et al. is therefore free of said residual monomers. It is recognized by the examiner that being free of residual monomers satisfies the limitation of being

below 10000ppm. Furthermore no such α,β-unsaturated carbonyl by-products are mentioned and this silence by Heard et al. is likewise concluded to be the result of none present. In the instance where residual monomers were a concern that resulted in either toxic byproducts or decreased process efficiency Heard et al. offers no solution.

Kim teaches the construction of a hydrogel (page 1, line 20) in which the residual monomer content is preferentially lowered based on the realization that residual monomers represent process inefficiency of said hydrogels (page 2, lines 7-10). Kim further teaches that method of lowering undesired residual monomer content are known in the art and specifically a method is known for reducing residual (meth)acrylic acid in water-absorbent gel polymers whereby the polymers are treated with vinyl addition compounds (i.e. reducing agents) such as sulfites (page 2, lines 12-18). Conventional reducing agents such as sodium bisulfite are shown to be applicable (page 9, lines 24-26).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have realized the invention of Heard et al. and decidedly incorporated the methods of decreasing residual monomer content taught by Kim due to the fact that residual monomer content was known to create process inefficiency (page 2, lines 7-10) and moreover in the cases where acrylamide may have been used it would have been understood by one of ordinary skill in the art that the residual monomeric form represents a toxic byproduct.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. (WO 00/45698) in view of Munro et al. (US 6,592,898).

Regarding claim 14, Heard et al. teaches the adhesive of claim 1 as seen above teach. It is reasonable conclude that due to the nature of the invention encompassing the claim limitations and consequently being composed of the same components in substantially the same amounts that the adhesive would inherently possess the same elastic modulus (G'). It is recognized by the examiner, however, that despite this inherency Heard et al. makes no explicit mention as to the elastic modulus of the adhesive.

Munro et al. teaches a bioadhesive used for electrically conductive hydrogel compositions with bioadhesive properties (column 1, lines 4-10) that is recognizably from the same field of endeavor as Heard et al. It is further taught by Munro et al. that the bioadhesive composition has an preferable elastic modulus (G') at 1rad/s of from 700 to 15,000Pa (column 3, lines 56-60).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have recognized the adhesive taught by Heard et al. and specifically combined the components within the acceptable ranges disclosed above in a manner as to achieve an elastic modulus at 1rad/s of from 700 to 15,000Pa in view of Munro et al. because the elastic modulus was known to be an important property in wetting/creep behavior and clearly should have been optimized accordingly.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kantner et al. (US 5,985,990) and Munro (US 2002/0026005A1) were both found to pertinent, but were not used in the formulation of the arguments seen above.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael N. Orlando whose telephone number is (571)-270-5038. The examiner can normally be reached on Monday-Friday, 7:30am-5:00pm, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571)272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER
10/31/07